UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. LIFESOY, INC., a corporation, and LONG H. LAI, an individual, Defendants.	Case No. 10CV1059JM(JMA) **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, has filed a Complaint for Permanent Injunction against Lifesoy, Inc. ("Lifesoy"), a corporation, and Long H. Lai, an individual (collectively, "defendants"). Defendants have appeared through counsel and have consented to the entry of this Consent Decree of Permanent Injunction (the "Decree") without contest and before any testimony has been taken. The United States of America has consented to this Decree and the parties have jointly moved for its entry.

THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 ("the Act").

3. Defendants violate 21 U.S.C. § 331(k) of the Act by causing ready-to-eat soy products, articles of food within the meaning of 21 U.S.C. § 321(f) (hereafter, "food"), to

become adulterated within the meaning of 21 U.S.C. § 342(a)(4). The articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health, or whereby they may have become contaminated with filth. Defendants also violate 21 U.S.C. § 331(dd) by failing to register with FDA in accordance to 21 U.S.C. § 350d.

4. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, holding, and distributing articles of food, at or from their facility located at 4849 University Avenue, San Diego, California, (the "San Diego facility"), and any other locations at or from which defendants, now or in the future, receive, prepare, process, pack, hold, or distribute any articles of food, unless and until:

(A) Defendants select an expert or experts (the "sanitation expert") having no personal or financial ties (other than a consulting agreement) to defendants or defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop and implement a written sanitation control program and to assure that the defendants' comply with the Current Good Manufacturing Practice (CGMP) requirements, 21 C.F.R. Part 110, and:

I. Defendants inform the United States Food and Drug Administration ("FDA") in writing of the name and qualifications of the sanitation expert as soon as they retain the expert;

II. The sanitation expert develops a written sanitation control program for manufacturing, preparing, packing, holding, and distributing articles of food, as described in Paragraph 4(A), and such plan is submitted to FDA prior to implementation;

III. Defendants receive written notification from FDA approving the sanitation control program developed by the sanitation expert;

IV. Defendants make the sanitation control program available and accessible (in

English, Spanish, or any other language(s) so that it is understood by all employees) to all their employees;

V. The sanitation expert develops a written employee training program that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and the sanitation expert provides the training to each employee and documents that each employee has received and understood the training;

VI. Defendants assign the responsibility and authority for implementing and monitoring the sanitation control program on a continuing basis to an employee who is trained in sanitation control requirements, and qualified and authorized to implement and monitor the sanitation control program;

VII. The sanitation expert inspects the defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein, to determine whether defendants have adequately established and implemented the FDA-approved sanitation control program, whether the defendants have adequately addressed the FDA investigators' inspectional observations listed on each Form FDA-483 issued to the defendants since November 2007, and whether the defendants comply with the CGMP requirements, 21 C.F.R. Part 110, and the Act; and

VIII. The sanitation expert certifies to FDA in writing that the defendants have adequately established and implemented the FDA-approved sanitation control program, have adequately addressed the Form FDA-483 observations, and comply with the CGMP requirements, 21 C.F.R. Part 110, and the Act and, as part of the certification, provides to FDA a written report describing in detail the actions the defendants have taken to ensure that, on an ongoing basis, they adequately implement the FDA-approved sanitation control program and comply with the CGMP requirements, 21 C.F.R. Part 110, and the Act;

(B) Defendants shall destroy under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved prior to implementation, in writing, by FDA, all raw ingredients and all in-process and finished articles of food in their custody, control, or possession at the time this decree is signed by the parties;

(C) FDA, as it deems necessary to evaluate defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, conducts inspections of the San Diego facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

(D) Any display or sales racks or container that defendants provide retailers are capable of refrigerating (or controlling the temperature of) the defendants' product;

(E) Defendants register with FDA under 21 U.S.C. § 350d, and the implementing regulations, 21 C.F.R. Part 1, Subpart H;

(F) FDA notifies defendants in writing that defendants appear to be in compliance with the requirements set forth in Paragraphs 4(A) through (E) of this Decree, the Act, and 21 C.F.R. Part 110; and

(G) Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to Paragraphs 4(A) through (F), at the rates set forth in Paragraph 7 below.

5. After defendants receive written notification from FDA pursuant to Paragraph 4(F) that they appear to be in compliance with Paragraphs 4(A) through (E) of this Decree, the Act, and 21 C.F.R. Part 110, defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are permanently restrained and enjoined from:

(A) directly or indirectly doing or causing any act that violates 21 U.S.C. § 331(k), by causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) after shipment of one or more of their components in interstate commerce;

(B) violating 21 U.S.C. § 331(dd) by failing to register with FDA in accordance to 21 U.S.C. § 350d; and

(C) failing to implement and continuously maintain the requirements of this Decree.

6. Representatives of FDA shall be permitted, without prior notice and as and when

FDA deems necessary, to make inspections of defendants' facility at its current location or at any new locations, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. Such inspections may, at FDA's discretion, include, but are not limited to, taking photographs and samples and examining and copying all records that relate to the receipt, processing, preparation, packing, holding, or distribution of any article of food. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

7. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate defendants' compliance with this Decree. The costs of such inspections shall be borne by defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.50 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

8. If any defendant violates this Decree and is found in civil or criminal contempt, defendants shall, in addition to other remedies, reimburse plaintiff for its attorney fees (including overhead), investigational expenses, expert witness fees, and court costs relating to such contempt proceedings.

9. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data submitted by defendants or the expert, or any other information, that defendants have failed to comply with any provision of this

Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify defendants in writing of the noncompliance and order defendants to immediately:

(A) Cease receiving, processing, preparing, packing, holding, and distributing any articles of food;

(B) Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

(C) Submit additional reports or information to FDA;

(D) Recall all articles of food that have been distributed or are under the custody and control of defendants' agents, distributors, customers, or consumers; or

(E) Take any other corrective actions that FDA, in its discretion, deems necessary to bring defendants into compliance with this Decree, the Act, and its implementing regulations.

10. Upon receipt of notification from FDA under Paragraph 9, defendants shall immediately and fully comply with the terms of the notice. All costs of such recall(s) and corrective actions shall be borne by defendants. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 9 shall be borne by defendants at the rates specified in Paragraph 7. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

11. Any cessation of operations as described in Paragraph 9 shall continue until defendants receive written notification from FDA that defendants appear to be in compliance with the Act, its implementing regulations, and this Decree.

12. Within ten (10) calendar days after the entry of this Decree, defendants shall provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to each and all of defendants' officers, agents, employees, attorneys, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Within thirty (30) calendar days of the date of entry

of this Decree, defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with the provisions of this Paragraph and identifying the names and positions of all persons who have received a copy of this Decree.

13. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including: a reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor entity or corporation; the creation or dissolution of subsidiaries or any other change in the corporate structure or identity of Lifesoy, or any other current or future food processing business of defendants; or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assignee at least thirty (30) calendar days prior to such sale or change of business. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) calendar days prior to such sale or change of business.

14. If defendants fail to comply with any of the provisions of this Decree, then defendants shall pay to the United States of America the sum of one thousand dollars ($1,000.00) in liquidated damages for each calendar day defendants are in violation of the Decree, and an additional one thousand dollars ($1,000.00) for each violation of this Decree.

15. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be submitted to the Director, FDA Los Angeles District Office, 19701 Fairchild, Irvine, California, 92612, and shall reference this civil action by case name and civil action number in such communications.

16. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

17. No sooner than seven (7) years after entry of this Decree, defendants may petition this Court for an order dissolving this Decree. If defendants have maintained, to FDA's satisfaction, a state of continuous compliance with this Decree, the Act, and all applicable regulations for seven (7) years preceding defendants' petition, the government will not oppose such petition.

18. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED:

Dated this 2nd day of June, 2010.

Hon. Jeffrey T. Miller
United States District Judge

We hereby consent to the entry of the foregoing Decree:

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